IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of: Michael Wandell et al.	Examiner: Lore Ramillano
Application No.: 10/706,321	Group Art Unit: 1797
Publication No.: 2005/0130310	Publication Date: June 16, 2005
Filed: November 12, 2003	Atty. Docket No.: 36664.00.0013
Title: **QUANTITATIVE ANALYSIS OF A BIOLOGICAL SAMPLE OF UNKNOWN QUANTITY**	

Mail Stop Appeal Brief—Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF PURSUANT TO 37 C.F.R. § 41.37

Dear Sir:

Appellants submit this brief further to the Notice of Appeal dated September 23, 2008, in the above-identified application.

TABLE OF CONTENTS

I. REAL PARTY IN INTEREST

Home Access Health Corporation is the assignee of all rights and interests in U.S. Patent Application No. 10/706,321 recorded before the USPTO on April 7, 2008, at Reel/Frame 020766/0530, and is the real party in interest in this Appeal. Appeal by an Applicant is proper under 37 C.F.R. § 41.31(a)(1).

II. RELATED APPEALS AND INTERFERENCES

To Appellant's knowledge, there are no related appeals or interferences filed, pending, or decided.

III. STATUS OF CLAIMS

Claims 4–15, 20–21, and 42 are pending.

Claims 4–15, 20–21, and 42 were twice rejected on December 12, 2007, and June 23, 2008, respectively, which are on final rejection and are thus appealed to this Board.

A copy of appealed claims 4–15, 20–21, and 42 as currently presented is attached in Appendix A.

Dependency: Claims 4, 6, and 42 are independent. Claim 5 is dependant upon claim 4, claim 7 is dependant upon claim 6, and claims 7–15 and 20–21 are dependant upon claim 42.

The originally filed application included 41 claims. Claim 42 was added during subsequent prosecution. Claims 22–41 were withdrawn from consideration as being drawn to a nonelected invention. Claims 1–3 and 16–19 were cancelled by Applicant. All appealed claims are currently twice rejected by a nonfinal Office Action. Twice-rejected claims may be appealed even if not in final rejection. 37 C.F.R. § 41.31(A)(1). No claims have been allowed or confirmed.

IV. STATUS OF AMENDMENTS

Dependant claims 5, 7, and 21 are original.

All claims, aside from claim 42, were first rejected on December 12, 2007, by the Examiner. On March 21, 2008, Applicant added claim 42 directed to a kit incorporating all features of claim 4. Dependant claims 8–15 and 20 were amended on March 21, 2008, only to the extent that they were made to depend upon newly added claim 42. The body of these claims has remained unchanged since they were filed in the original application. Claims 4 and 6 were amended to include the subject matter of claim 1 and were rewritten in independent format. No substantive amendments were made to these claims. A final rejection of all claims was issued on June 23, 2008.

A telephone conference was held on August 8, 2008. Applicant filed an after-final response on August 25, 2008, without amendments to the claims. The Examiner maintained her final rejection on September 11, 2008, in an Advisory Action. Applicant filed a Pre-Appeal Brief on September 23, 2008. A Notice of Rejection from the Pre-Appeal Panel was received on December 10, 2008.

V. SUMMARY OF CLAIMED SUBJECT MATTER

References herein are made to the page and paragraph numbers of the application as filed. Medical patients and their doctors do not always have access to medical institutions, but all patients and doctors have access to the postal service. Sending liquid blood specimens through the mail is impractical. The collection by patients of large or fixed quantities of liquid in a vial to be mailed is problematic. One solution is to prick a finger using a pricking device, place the finger over an absorbing tissue, and collect blood that dries on the absorbing tissue for optimal postal delivery. (See paras. 3 and 4.) Claims 4 and 6 and their dependent claims are directed to a fluid collection device 900 shown in FIGS. 9–10 (front and back). Claim 42 and its dependant claims are directed to a kit 1100 shown in FIG. 11 where the fluid collection device 900 is shown as part of the kit 1100.

FIG. 9

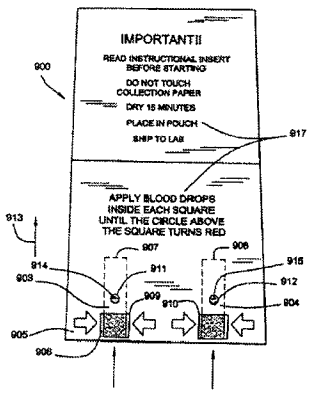


FIG. 10

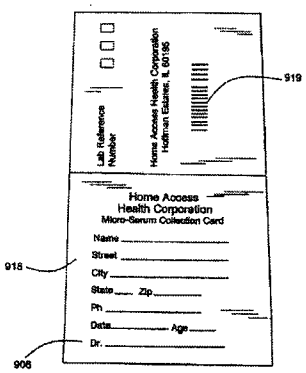
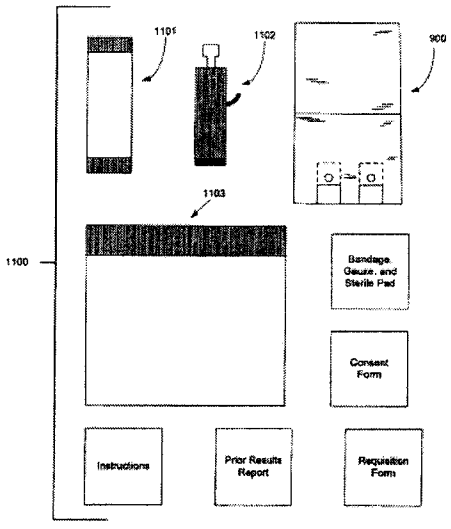


FIG. 11



Figures 9–11 of U.S. Patent Application No. 10/706,321

Remote testing of blood allows patients to preserve some degree of anonymity. During the spread of HIV in the late 80s, the need for remote testing became especially important. (See para. 4.) There is also a need for remote testing of blood for different medical conditions, such as high cholesterol, lipid profiles, triglycerydes. (See para. 6.) Remote testing can be done by

pricking a finger and placing a few drops of blood on an absorbent material, which becomes a dried blood specimen. (See para. 9.) The device includes a fluid collector 903, 904 as shown in FIG. 9 (See para. 44.) This fluid collector is shown in FIG. 9 as a long, rectangular strip and is disposed between a superstrate sheet 905 shown in FIG. 9 and a substrate sheet 906 shown in FIG. 10. (See para. 44.)

The fluid collector shown by the dashed lines in FIG. 9 is an absorbent substrate (see para. 50) coated with saccharide, made of a mat of glass fibers, and at least substantially coated with polyvinyl alcohol. (See paragraph 51.) The fibers have a size that substantially prevents lysing of red blood cells while permitting at least substantial separation of serum from red blood cells via differential wicking. (See para. 51.) A user places his finger on an aperture 909, 910, said aperture being made in the superstrate sheet 905, and brings the blood drop at the end of the finger in contact with the fluid collector through the aperture. The blood is absorbed in the absorbent substrate between the arrows as shown in FIG. 9. The blood migrates up along arrow 913 until the fluid collector visible via the secondary aperture 911, 912 becomes red with red blood cells. (See para. 44.)

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Only one group is on appeal. Claims 4–15, 20–21, and 42 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Quattrocchi (U.S. Patent No. 6,014,438) in view of Fitzgerald et al. (U.S. Patent No. 6,528,321).

VII. ARGUMENT

All independent claims of the group on appeal are directed to a kit or a fluid collection device where the phrases "said superstrate having an aperture defining a blood receiving opening" (claims 4 and 42) and "said superstrate having a pair of apertures, each defining a blood receiving opening" (claim 6) are at issue. The term to be reviewed on appeal is "aperture" within the context of Applicant's claims.

The Examiner explains that "Quattrocchi further discloses a fluid collection device comprising a pair of fluid collectors, and a single superstrate, said fluid collectors ordinarily not being in fluidic contact with one another and each being generally fixed with respect to said superstrate, said superstrate having a pair of apertures, each defining a blood receiving opening and permitting access to a respective one of said fluid collectors." (See June 23, 2008, Final Office Action, p. 3.)

In response to Applicant's request for clarification, the Examiner explained, "In response to applicant's response that Quattrocchi does not have an opening to provide access to a fluid collector, examiner disagrees. During examination, the claims may be interpreted as broadly as their terms reasonably allow. Here, it appears that Quattrocchi's specimen selections (58) may be interpreted to be 'apertures,' because Quattrocchi discloses having an absorbent sample sheet (56), which has small openings to allow the fluid to flow through the sheet. Quattrocchi further discloses in col. 10, lines 33–43, that such specimen sections may be interpreted as apertures because he discloses having the blood sample 'fill the specimen section on the card.'" (See June 23, 2008, Final Office Action, p. 7.)

During patent examination, pending claims must be given their broadest reasonable interpretation consistent with the specification. *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir.

2005). Words of a claim must be given their plain meeting unless this meaning is inconsistent with the specification. *In re Zletz*, 893 F.2d 319 (Fed. Cir. 1989). Applicant's claims are directed to a superstrate having one or two apertures defining a blood receiving opening and permitting access to said fluid collector.

The term "aperture" can only be found in the claims of the application and at para. [0044] of the specification. The specification provides "at least one aperture (two shown as 909, 910) by which a user may fluidically transfer blood to the collector ... To use the device, a user dispenses blood onto the collector, whereby some or all of the blood wicks in the direction shown by arrow 913 until the portions 914, 915 of the collectors 903, 904 visible through the secondary apertures 914, 915 become tinted, whereupon the user is provided with an indication that sufficient blood has been collected." Apertures are openings made in the superstrate to allow a user to place a pricked finger over the fluid collector and not dirty the superstrate. The specification does not give the term "aperture" any special meaning. The term must then be given its plain meaning.

The *Merriam-Webster's Collegiate Dictionary*, 10th ed. defines "aperture" as an opening or open space: hole. In turn, "opening" is defined as something that is open. (See Exhibit A attached hereto.) The term "aperture" is a simple term and is regularly used by claim draftsmen, including Applicant. In *Mechanics of Patent Claim Drafting*, 2nd. ed., Landis explains, "Do not claim holes positively or make them claim elements. Holes are nothing; you cannot claim nothing. Claim "a [member] having a hole, groove, slot, aperture, etc." Section 23 of *Mechanics of Patent Claim Drafting*, 2nd. Ed. A copy of the relevant pages from this reference is attached as Exhibit B. Applicant's claims are directed to a superstrate with one or two apertures.

In the *prima facie* case, the Examiner cites U.S. Patent No. 6,014,438 (Quattrocchi). Quattrocchi is a decade-old technology owned and created by Applicant. Figures 4A and 4B of the reference show the old fluid collection device of that reference are shown below.

FIG. 4A

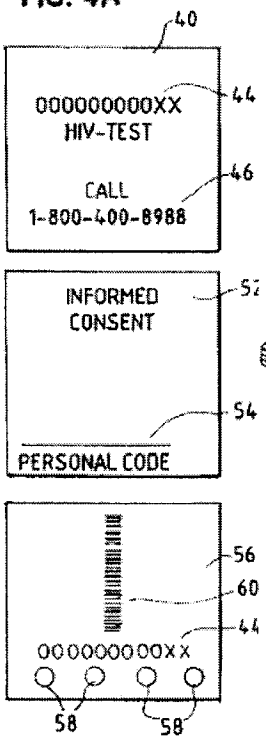
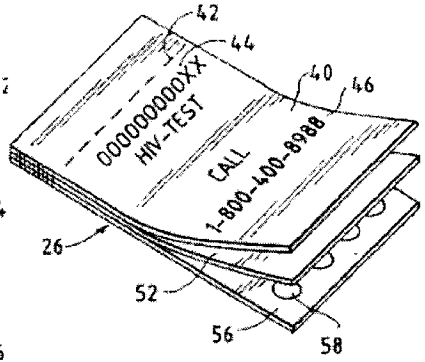


FIG. 4B



Applicant directs this Board to elements 58. The circles are not openings (i.e., holes) made in the last sheet of paper on this figure, they are small ink circles drawn to indicate where the finger must be placed. This older technology is simpler and has obvious disadvantages. It consists of three card stacked on top of each other. The user was required to rip the cards along dotted line 42, place the finger on a small circle 58 made of ink in the last page 56, and then mail the page to the laboratory. The blood would hopefully fill in the small ink circle that would be punched out of the card and placed in a device for measure.

Quattrocchi at col. 7, ll. 32–42 explains this process:

> FIGS. 4A and 4B schematically illustrate one form of blood specimen collection card 26 which is preferably configured in a diagnostic form having three (3) parts. The first part is a removable top sheet 40. Perforations 42 are preferably provided to enable the person being tested to remove the top sheet 40 from the remainder of the collection card 26.

> Printed on the top sheet 40 is information that the person being tested needs to retrain after the remainder of the collection card 26 is sent for analysis. Col. 6, ll. 54–63.
>
> The second part of collection card 26 is an informed consent form 52. The informed consent form 52 contains a series of statements that the person being tested must read, understand, and acknowledge before a laboratory can perform any test on the specimen. Col. 7, ll. 23–26.
>
> In its illustrated form, the third part of collection card 26 is a blood specimen sample sheet 56. Sample sheet 56 is at least in part a cotton fiber filter paper preferably like that manufactured by Schleicher and Schuell. Sample sheet 56 has a blood collection area specifically designated thereon. In the illustrated embodiment, four similarly shaped sections 58 are outlined thereon for deposit of a specimen in each section. The sections 58 are outlined using black biological ink so that the ink will not interfere with the specimen and an accurate test result can be obtained.

The old technology requires the entire sheet to be made of expensive blood-retaining media. Black biological ink circles are drawn on a flat piece of paper, and users were required to place the finger in the circle and try to get the blood to diffuse over the entire area of the circle. Applicant believes Board members are familiar with this old technology. The ink is biological because the blood, as it flows from the inside of the circle to the outside of the circle must not be tainted with nonbiological ink.

In this old technology, there is no built-in protection for the blood sample when it is mailed out, and the sample would rub directly against other bodies within an envelope during transportation. Once at the laboratory, a circular punch system was used to remove the surface area inside the ink circles to collect the part of the substrate to dilute for measurement. If part of the circle was still white, the measure would be skewed.

The Examiner's confusion here is clear. Examiner's position is best summarized by the continuation comment to the Advisory Action of September 11, 2008: "the Office takes the position that specimen sections (58) may be broadly interpreted to be openings." Broadly construed, the specimen sections 58, made of small biological ink circles drawn on a page cannot be construed, even if given their broadest reasonable interpretation to apertures.

Further, Applicant's claims read, "an aperture defining a blood receiving opening and permitting access to said fluid collector." (Claim 42). The small ink circles 58 made of biological ink as shown on FIG. 4B of Quattrocchi cannot be reasonably be analogized the elements found in that claim.

Rules are given to the Examiner if she wants to constitute a valid *prima facie* case where ink circles constitute apertures. She must either prove that Applicant's specification supports this particular meaning—that the plain meaning of these words support this interpretation—or that one of ordinary skill in the art agrees with the Examiner. MPEP § 2111. The position taken by the Examiner is contrary to almost every patent claim recorded with this Office. Apertures and openings in a media are precisely that: an aperture or an opening. Applicant asks this Board under what possible circumstance can writing or printing the number 8 on a piece of paper result in creating two apertures?

The use of the term "aperture" and "opening" is well established under modern patent practice. Apertures and openings are normal terminology used to claim holes. The plain meaning of these words is well known and unambiguous. Quattrocchi is a device with a fluid collector having neither an aperture nor an opening. The Examiner's position is contrary to common sense and patent law. The Examiner cannot argue that Applicant's apertures should be broadly construed to include surface areas within ink circles. Accordingly, Applicant requests reconsideration and withdrawal of the rejection and issuance of a Notice of Allowance for all pending claims.

Finally, this argument would not be complete without attempting to understand why the Examiner misconstrues the reference and believes ink circles drawn on a surface of a card can be analogized to openings or apertures made in the card. The Examiner argues, "Here, it appears

that Quattrocchi's specimen selections (58) may be interpreted to be 'apertures,' because Quattrocchi discloses having an absorbent sample sheet (56), which has small openings to **allow the fluid to flow through the sheet.** Quattrocchi further discloses in col. 10, lines 33–43, that such specimen sections may be interpreted as apertures because he discloses having the blood sample 'fill the specimen section on the card.'" (See June 23, 2008, Final Office Action, p. 7.)

The Examiner must be reading "the fluid to flow **through the sheet**" as blood moving from a top surface to a bottom surface of the card (e.g., front to back), and hence the circle must by default be an opening of some type made in the sheet. This interpretation is incompatible with any reasonable interpretation of the reference. The members of this Board are familiar with strip technology. A thin absorbent substrate is placed in contact with a fluid (e.g., urine, blood, etc.) at one location and the fluid diffuses through the sheet to cover the other extremity. In the case of the circle on the sheet of the reference, the blood flows through the sheet until it reaches the ink circle. Otherwise there would be no point in using the biological ink except if the ink is in the path of the flow of the blood as described in the reference. The goal is not to soak with blood the reverse portion of the Quattrocchi card 56 but to allow sufficient time and blood for the blood to migrate (flow through) the circle and reach all of the area inside. Applicant is well versed with the Quattrocchi technology, having invented it and used it commercially for over a decade.

VIII. CONCLUSION

If this Board sides with the Examiner, it must conclude that if a pen is used to draw an ink circle on a piece of paper, an apertures or an opening has been created in the sheet. The terms apertures and openings are terms of art in patent drafting to claim holes that cannot be claimed statutorily. The use of the expression "flows through" in the cited reference, when read for a filtration or absorbing media, represents lateral flow as clearly explained in detail in the

reference's specification. Instructions on how to paint a curtain read, "Place the curtain in contact with the ink, it will flow though the tissue until it reaches mark A." Surely this cannot be analogized with a curtain having an aperture or an opening allowing the ink to flow though the curtain.

Obviousness rejections must not be creative associations by Examiners of references drawn unreasonably. Valid obviousness rejections place before an inventor a combinations of enabling prior art that can be presumed to be known by the inventor from a closely related field and that together form the invention under some motivation and expectation of success. In this case, all of the basic elements associated with a proper § 103(a) rejection are missing. Applicant's own invention cited as a reference does not teach a medium with an opening. For the reasons advanced above, Appellant submits that the Examiner erred in rejecting pending claims 4–15, 20–21, and 42 and respectfully requests reversal of the decision of the Examiner.

Respectfully submitted,

Date: March 23, 2009

By: _____
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APPENDIX A

CLAIMS ON APPEAL

GROUP I—Claims 4–15, 20–21, and 42

4. A fluid collection device comprising a fluid collector with an absorbent substrate coated with a saccharide, said substrate comprising a mat of glass fibers at least substantially coated with polyvinyl alcohol, said fibers defining a plurality of pores, the pores in said mat having a pore size effective to at least substantially prevent lysing of red blood cells while permitting at least substantial separation of serum from red blood cells via differential wicking and a superstrate, said fluid collector being generally fixed with respect to said superstrate, said superstrate having an aperture defining a blood receiving opening and permitting access to said fluid collector.

5. A fluid collection device according to claim 4, said fluid collector having a first end and a second end, said aperture permitting fluidic access to said first end of said collector, said superstrate having a second aperture relatively proximal said second end of said fluid collector.

6. A fluid collection device comprising a pair of fluid collectors, each comprising an absorbent substrate coated with a saccharide, said substrate comprising a mat of glass fibers at least substantially coated with polyvinyl alcohol, said fibers defining a plurality of pores, the pores in said mat having a pore size effective to at least substantially prevent lysing of red blood cells while permitting at least substantial separation of serum from red blood cells via differential wicking and a single superstrate, said fluid collectors ordinarily not being in fluidic contact with one another and each being generally fixed with respect to said superstrate, said superstrate

having a pair of apertures, each defining a blood receiving opening and permitting access to a respective one of said fluid collectors.

7. A fluid collection device according to claim 6, said superstrate comprising a second pair of apertures, each of said fluid collectors having a first end and a second end, said blood receiving openings permitting respectively fluidic access to the first end of one of said fluid collectors, said second pair of apertures each being respectively relatively proximal said second end of one of said fluid collectors thereby defining a pair of gangs.

8. A kit according to claim 42, further comprising instructions for using the fluid collection device.

9. A kit according to claim 8, wherein said instructions are integral with said device.

10. A kit according to claim 8, wherein said instructions are separate from said device.

11. A kit according to claim 42, further_comprising a requisition form, said requisition form permitting indication of the type of test to be conducted on the fluid to be collected by the device.

12. A kit according to claim 11, wherein said requisition form lists a plurality of test types.

13. A kit according to claim 42, further_comprising a dessicant, said dessicant being present in an amount effective to provide a dessicating protective effect on a blood fluid specimen.

14. A kit according to claim 13, wherein said dessicant comprises silica.

15. A kit according to claim 14, wherein said dessicant is contained in a porous pouch.

20. A kit according to claim 42 further comprising a lancet, instructions for using the kit, a dessicant, said dessicant being present in an amount effective to provide a dessicating protective effect on a blood fluid specimen collected in said device, and a barrier film pouch sized for receiving said fluid collection device and said dessicant.

21. A kit according to claim 20, further comprising a requisition form permitting indication of the type of test to be conducted in the fluid to be collected by the device.

42. A kit comprising: a fluid collection device having a fluid collector with an absorbent substrate coated with a saccharide, said substrate comprising a mat of glass fibers at least substantially coated with polyvinyl alcohol, said fibers defining a plurality of pores, the pores in said mat having a pore size effective to at least substantially prevent lysing of red blood cells while permitting at least substantial separation of serum from red blood cells via differential wicking and a superstrate, said fluid collector being generally fixed with respect to said superstrate, said superstrate having an aperture defining a blood receiving opening and permitting access to said fluid collector.

APPENDIX B

EVIDENCE APPENDIX

Patents and Patent Application Publications

U.S. Patent No. 6,014,438 (issued Jan. 11, 2000) to Quattrocchi, of record, initially entered by Examiner in USPTO Office Action, page 6, ¶ 15 (mailed December 12, 2007).

U.S. Patent No. 6,528,321 (published Mar. 4, 2003) to Fitzgerald et al., of record, initially entered by Examiner in USPTO Office Action, page 6, ¶ 15 (mailed December 12, 2007).

United States Patent and Trademark Office, Office Actions Of Record

USPTO Request for Restriction, (mailed: Sept. 20, 2007).

USPTO non-final Office Action, (mailed: Dec. 12, 2007).

USPTO final Office Action, (mailed: June 23, 2008).

USPTO Interview Summary, (mailed: August 27, 2008).

USPTO Advisory Action, (mailed Sept. 11, 2008).

Applicant's Correspondence

Application as filed, November 12, 2003.

Information Disclosure Statement, January 6, 2006.

Information Disclosure Statement, October 3, 2007.

Amendment and Response to USPTO Request for Restriction mailed on Sept. 20, 2007 (dated October 3, 2007).

Amendment and Response to USPTO nonfinal Office Action mailed on Dec. 12, 2007 (dated March 12, 2008).

Amendment and Response to USPTO final Office Action mailed on June 23, 2008 (dated August 21, 2008).

APPENDIX C

RELATED PROCEEDINGS

[NONE]